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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: Inviting comments and suggestions from stakeholders on Pediatric Medical Devices Public-Private Partnership

AGENCY: National Institutes of Health, HHS.

ACTION: Request for Information.

SUMMARY: The National Institute of Child Health and Human Development (NICHD), in collaboration with the National Institute of Biomedical Imaging and Bioengineering (NIBIB), seek comments and input focusing on challenges, gaps, clinical needs, and research opportunities related to Pediatric Medical Devices (PMD) to inform priorities for a Public Private Partnership (PPP) to catalyze the national ecosystem. Such ecosystem will focus on optimizing the translation of technological advancements into medical devices designed, evaluated, and approved for pediatric populations to improve quality of life in this population. These comments are requested from public and private stakeholders such as, but not limited to, innovators, researchers, academic and medical centers, small- and large-scale industries, non-profit organizations, patients, providers, advocacy groups, payors, and federal agencies.

DATES: The Request for Information is open for public comment and will be accepted through Sept 21, 2022, to ensure consideration.

ADDRESSES: Responses should be limited to one to two page(s) and marked with this RFI identifier "NOT-EB-22-008" in the email subject line as well as in the title of the response. Responses should be directly submitted to peds.medtech@nih.gov.

FOR FURTHER INFORMATION CONTACT: Questions about this request for information should be directed to, Afrouz Anderson, PhD, National Institute of

Biomedical Imaging and Bioengineering (NIBIB), National Institutes of Health, 6707 Democracy Boulevard, Suite 200, Bethesda, MD 20892, peds.medtech@nih.gov, 301-496-4558.

SUPPLEMENTARY INFORMATION: This RFI is in accordance with the NIH Reform Act of 2006, 42 U.S.C. Sec. 282, as amended. Catalyzing and unifying the national ecosystem around pediatric medical devices will necessitate leveraging collective opportunities, such as through the formation of a multi-stakeholder Public Private Partnership (PPP) to address the existing challenges in development, optimization, and translation of pediatric medical devices.

Despite numerous legislative, regulatory, and scientific efforts of the recent past, there has been little change in the number of devices being developed, reviewed, and/or approved for use in the pediatric population in the United States. The cause of this public health problem is multifold:

- Real and perceived ethical considerations of carrying out trials in pediatric patients.
- The heterogeneous developmental range of children, from birth to 21 years.
- Lack of access to disease- and age-specific patient sets, and experienced clinical-trial infrastructure.
- Unclear regulatory pathways and financial environment (i.e., unpredictable reimbursement).
- A lack of technical innovation for approaches to meet pediatric-specific needs.
- Lack of clear value proposition to device manufacturers and industry partners.

Such problems have caused difficulties such as off-label use of devices in children, often without clear instructions or with non-standard modifications that create further complications and risks. Additionally, many conditions for children that could be treated

via a device are not pursued. Pediatric patients with serious or life-threatening diseases that are often in greatest need might only have access to an investigational medical device without an appropriate level of evidence.

Information Requested

NICHD and NIBIB seek information and actionable recommendations on research gaps, needs, best practices, innovative study designs and measurement, resources and data resources, and opportunities to inform a PPP to enhance pediatric medical devices space.

Specifically, respondents are asked to briefly address the following topics or categories in the context of Pediatric Medical Devices. Comments are strongly encouraged to address unique challenges of using pediatric medical devices on health disparity populations. NIH defines health disparity populations as racial and ethnic minority populations, less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM), and any subpopulations that can be characterized by two or more of these descriptions. For more information, please refer to NIH definition of Health Disparity (https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html#:~:text=NIH%20defines%20health%20disparity%20populations,or%20more%20of%20these%20descriptions.)

1) **Potential partners to ensure success of public-private partnership to advance the national PMD ecosystem. Some of these challenges pertain, but are not limited to, involvement and integration of:**
    a) Philanthropic and non-profit organizations
    b) Patient advocacy groups

c) Primary care providers, specialists and clinicians, clinical trialists, and pediatric patients
d) Financial experts
e) Regulatory science experts to evaluate new and existing regulations in PMD

2) **Involvement of Private Industry while considering factors such as:**
   a) Small market size in pediatric medical devices being one of the key barriers for industry participation
   b) Identifying approaches to de-risk development and commercialization of PMD
   c) Federal efforts to assist further small companies
   d) Overcoming manufacturing, clinical trials, logistical and regulatory burdens
   e) Engineering and manufacturing challenges for evaluation of feasibility, validation and scale-up strategies of device prototype and relative costs

3) **Priorities in Pediatric Medical Device innovation, research, and commercialization such as:**
   a) Accelerating PMD Research & Development, including, but not limited to, point of care technologies in response to Health Emergencies
   b) Specific preclinical and clinical research areas to enhance innovation in pediatric medical devices
   c) Projects focusing on development of technologies based on specific disease, conditions, and patient population
   d) Reduce off-label usage of adult medical devices for pediatric patients
   e) Resources and support for innovators, small business concerns to enhance successful development and commercialization of PMD designed and tested for pediatric indications

f) Building inclusive, diverse, and transdisciplinary workforce. For more information on diverse workforce, please refer to the Notice of NIH's Interest in Diversity NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html.)

4) **Accountability measures to evaluate the program success in areas such as, but not limited to:**
   a) Performance and accomplishment of public private partnership
   b) Number of products and devices that obtain regulatory approval
   c) Improvement of processes for PMD development and commercialization

5) **Clinical Trial infrastructure, data sharing, and protocol standardization such as:**
   a) Establishment of hospital-based and decentralized clinical trials networks to evaluate and validate new technologies and therapeutic devices.
   b) Issues pertaining to number of clinical sites
   c) Patient reported outcomes
   d) Challenges related to patient enrollment and limited dataset
   e) Data science expertise, such as biostatistics, to address issues related to clinical trial database
   f) Standardization of data and protocol integration across various health care settings

6) **Reimbursement Challenges for Pediatric Medical Devices:**
   a) Exploring reimbursement incentive strategies for Pediatric Medical Device innovators
   b) Involvement of Federal agencies such as Centers for Medicare and Medicaid (CMS)

c) Interaction with insurance companies during commercialization planning process

7) Any other topics which may be relevant for NIH to enhance the national pediatric medical device ecosystem via public-private partnership.

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable information or any information that you do not wish to make public. You may voluntarily include your name and contact information with your response. If you choose to provide NIH with this information, NIH will not share your name and contact information outside of NIH unless required by law. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government will use the information submitted in response to this RFI at its discretion. Other than your name and contact information, the Government reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements. This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

Afrouz A. Anderson,

Program Director,

National Institute of Biomedical Imaging and Bioengineering,

National Institutes of Health.

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